



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 19 1999

4906 '99 MAY 20 P1:32

The Honorable Chris John
House of Representatives
Washington, D.C. 20515

Dear Mr. John:

Thank you for your letter of April 26, 1999, also signed by fifteen of your colleagues concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest (CSPI). FDA published a request for comments on this petition in the Federal Register of January 21, 1999.

You express concern that the CSPI petition may be an attempt to circumvent the established process for dealing with molluscan shellfish in this country, namely that process utilizing the Interstate Shellfish Sanitation Conference (ISSC). You highlight the effectiveness of the Interim Control Plan developed by the ISSC and encourage additional educational and research efforts to improve the quality of shellfish as a reasoned and balanced manner to reduce oyster related illnesses without causing undue harm to the shellfish industry. And you request our assistance through the ISSC in establishing guidelines and priorities for these educational programs.

We appreciate your thoughtful comments and we have entered them into the Administrative Record for this petition. They will be reviewed in the Agency's deliberations on this petition.

Please contact us if we may be of further assistance in this matter. A similar letter has been sent to your co-signers.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

98P-0504

cc: Dockets Management Branch
(Docket No. 98P-0504)

AN818

United States Senate

WASHINGTON, DC 20510-1804

April 26, 1999

Jane E. Henney, Commissioner
U.S. Food and Drug Administration
5600 Fisher's Lane
Rockville, MD 20857

Dear Commissioner Henney:

Congress, the Food and Drug Administration (FDA), the Interstate Shellfish Sanitation Conference (ISSC), and the shellfish industry continue to recognize the risks associated with *Vibrio vulnificus* to certain high risk individuals when they consume raw molluscan shellfish. The recent petition submitted to the FDA by the Center for Science in the Public Interest appears to be trying to circumvent the established process for dealing with molluscan shellfish in this country. We hope that your agency will steer this effort back into the appropriate forum.

The ISSC has made commendable efforts over the last few years to address this issue in a fair and practical process. The adoption of the Interim Control Plan, and subsequent actions by industry to meet the guidelines of the Plan, has improved the National Shellfish Sanitation Program in a practical way. The industry in the Gulf has been willing to change its handling practices to improve the quality and wholesomeness of oyster products.

We encourage efforts to get industry to reduce oyster related illnesses by developing additional methods to improve the quality of shellfish. However, restrictive control measures for added consumer protection not based on scientific research may cause undue harm to the shellfish industry, especially in the Gulf of Mexico. In addition, such efforts are contrary to the reasonable approach the Conference has taken thus far.

We want to reiterate our support for a balanced and practical program based on consumer education and information that is supported by scientific research. Moreover, we continue to support funding for educational programs that address *vibrio vulnificus*. We also want to encourage the ISSC to continue its efforts in this arena while researchers continue to develop additional practical strategies. Again, we firmly agree that any future ISSC policies should be based on risk assessments utilizing accurate scientific data.

As such, we will continue our support of educational responses to *vibrio vulnificus* through federally funded programs. We also support the continuation of industry expenditures to further educational efforts. We would appreciate the FDA working with us through the ISSC process in establishing guidelines and priorities for these educational programs.

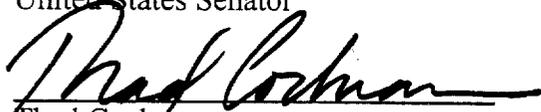
No 99- 2975

Jane E. Henney
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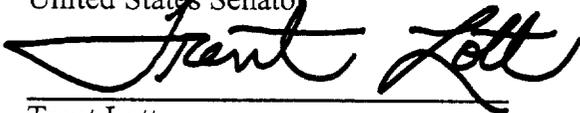
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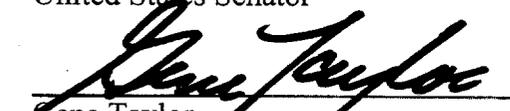
John B. Breaux
United States Senator



Thad Cochran
United States Senator



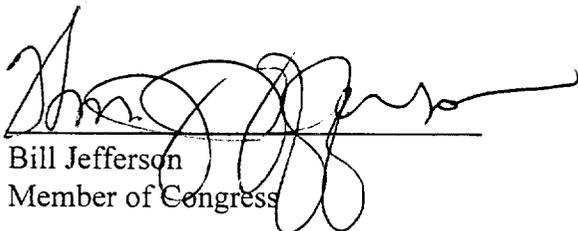
Trent Lott
United States Senator



Gene Taylor
Member of Congress



Richard Baker
Member of Congress



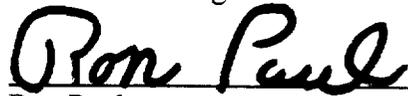
Bill Jefferson
Member of Congress



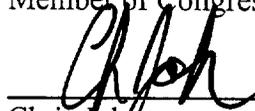
Mary L. Landrieu
United States Senator



W.J. Billy Tauzin
Member of Congress



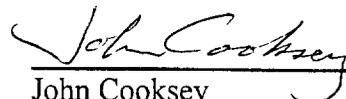
Ron Paul
Member of Congress



Chris John
Member of Congress



Allen Boyd
Member of Congress



John Cooksey
Member of Congress

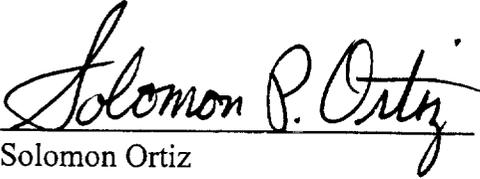


Nick Lampson
Member of Congress

Jane E. Henney

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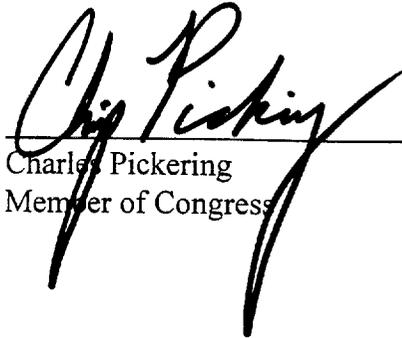
April 26, 1999



Solomon Ortiz
Member of Congress



Joe Scarborough
Member of Congress



Charles Pickering
Member of Congress